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**United States Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/267,963    03/12/99    MIYAZONO

K    LUD-5539.1-C

024972    HM12/0606  
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EXAMINER

ROMEO, D

ART UNIT

PAPER NUMBER

1647  
DATE MAILED:

16  
06/06/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Interview Summary

Application No.  
09/267,963

Applicant(s)  
Miyazano et al.

Examiner  
David Romeo

Group Art Unit  
1647



All participants (applicant, applicant's representative, PTO personnel):

(1) David Romeo (3) \_\_\_\_\_

(2) Mary Anne Schofield (4) \_\_\_\_\_

Date of Interview 5 Jun 2001

Type: a) ☒ Telephonic b) ☐ Video Conference  
c) ☐ Personal [copy is given to 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No. If yes, brief description:

Claim(s) discussed: 28

Identification of prior art discussed:

Agreement with respect to the claims f) ☐ was reached. g) ☒ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments:

Discussed restriction requirement mailed 05/21/01. Although the claims are directed to the same method results the means used to achieve the results are independent and patentably distinct. Claim 28 was restricted because it was unclear if an "agent which inhibits ALK-1" is the same as, generic to, or different from an "agent which inhibits phosphorylation of Smad1".

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

i) ☒ It is not necessary for applicant to provide a separate record of the substance of the interview (if box is checked).

Unless the paragraph above has been checked, THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

DAVID ROMEO  
PRIMARY EXAMINER  
ART UNIT 1647

## Interview Summary

Application No.  
09/267,963

Applicant(s)  
Miyazano et al.

Examiner  
David Romeo

Group Art Unit  
1647



All participants (applicant, applicant's representative, PTO personnel):

(1) David Romeo (3) \_\_\_\_\_  
(2) Mary Anne Schofield (4) \_\_\_\_\_

Date of Interview 14 May 2001

Type: a) ☒ Telephonic b) ☐ Video Conference  
c) ☐ Personal [copy is given to 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No. If yes, brief description:

Claim(s) discussed: 14-20 and 28

Identification of prior art discussed:

Agreement with respect to the claims f) ☐ was reached. g) ☐ was not reached. h) ☒ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments:

See the Attached proposed examiner's amendment.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

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Art Unit: 1647

**Proposed EXAMINER'S AMENDMENT**

~~1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.~~

~~Authorization for this examiner's amendment was given in a telephone interview with Mary Anne Schofield on May 14, 2001.~~

2. The application has been amended as follows:

14. A method of inhibiting expression of a gene, expression of which is activated by phosphorylated Smad1 or phosphorylated Smad5, comprising contacting a cell which expresses said gene and which presents ALK-1 on its surface with an inhibitor, wherein said inhibitor inhibits the binding of TGF- $\beta$  to ALK-1, wherein the inhibition of said binding inhibits the phosphorylation of Smad1 or Smad5.

Cancel claims 15, 17-19.

28. A method for identifying a gene whose activation is effected by phosphorylated Smad1 or phosphorylated Smad-5, comprising contacting a first sample of cells, which express ALK-1 and which express and phosphorylate Smad1 or Smad-5, with TGF- $\beta$  and an agent that inhibits the binding of TGF- $\beta$  to ALK-1, wherein the inhibition of said binding inhibits the

Art Unit: 1647

phosphorylation of Smad1 or Smad5, removing transcripts of said first sample of cells, and

comparing said transcripts with transcripts of a second sample of said cells treated with TGF- $\beta_1$  <sup>and</sup> <sup>DR</sup> 5/14/1

not treated with said agent, wherein any differences there between are transcripts of genes whose

activation is effected by phosphorylation of Smad1 or Smad-5.